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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/678,134	10/04/2000	Peter J. Wilk	W07-473	5978

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COLEMAN SUDOL SAPONE P.C.
714 COLORADO AVENUE
BRIDGEPORT, CT 06605-1601

EXAMINER	
ODLAND, KATHRYN P	
ART UNIT	**PAPER NUMBER**
3743	6

DATE MAILED: 12/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/678,134	WILK, PETER J.	
	Examiner	Art Unit	
	Kathryn Odland	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *4-6,9,12,15 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7,8,10,11,13,14 and 16-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *4-6,9,12,15 and 21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Claims 4-6, 9, 12, 15, and 21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

Response to Amendment

This is a response to the amendment dated November 20, 2003. Claims 1-3, 7, 8, 10, 11, 13, 14, and 16-20 are pending. The amended title is acknowledged and accepted.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-3, 7, 10, 11, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schweich, Jr. et al. in US Patent No. 5,961,440.

Regarding claim 1, Schweich, Jr. et al. disclose a method for improving cardiac function via inserting a compressive device (such as 16 with 20, etc.) into a patient in a region including the patient's heart; and after inserting the compressive device into the patient, operating the compressive device to bring opposite walls of only one ventricle of the patient's heart into at least proximity, as recited in column 2, lines 55-67, columns 7-8

and seen in figures such as 18. However, Schweich, Jr. et al. do not explicitly recite to bring opposite walls into contact with one another to thereby constrict and close off a lower portion of one ventricle of the patient. On the other hand, although not shown as contacting, it is within the scope of the invention and obvious to one with ordinary skill in the art to assure that the device of Schweich, Jr. et al. is drawn tightly enough to bring the walls into contact for the purpose of further treating congestive heart disorder by closing off the lower portion of the ventricle.

Regarding claim 2, Schweich, Jr. et al. as modified disclose that as applied to claim 1, as well as, operating of the compressive device that includes applying the compressive device to only a lower portion of one the lower portion of one ventricle of the patient's heart, as recited in column 2, lines 55-67, columns 7-8 and seen in figures such as 18. Again, although not explicitly recited, it is it is within the scope of the invention and obvious to one with ordinary skill in the art to assure that the device of Schweich, Jr. et al. is drawn tightly enough to bring the walls into contact for the purpose of further treating congestive heart disorder by closing off the lower portion of the ventricle.

Regarding claim 3, Schweich, Jr. et al. as modified disclose that as applied to claim 2, as well as, a ventricle that is the left ventricle of the patient's heart, as recited in columns 7-8 and seen in figures such as 18.

Regarding claim 7, Schweich, Jr. et al. as modified disclose that as applied to claim 1, as well as, a compressive device that includes a tensile member, the inserting of the tensile member the includes introducing the tensile member through a catheter (such as 60), as recited in columns 7-8 and seen in figures such as 18.

Regarding claim 10, Schweich, Jr. et al. a method for improving cardiac function via inserting a tensile member (such as 16 with 20, etc.) into a patient; and deploying the tensile member in the patient's heart so as to effectively constrict a lower or apical portion only of only a left ventricle of the patient's heart, thereby reducing the volume of the left ventricle and only the left ventricle of the patient's heart, as recited in column 2, lines 55-67, columns 7-8 and seen in figures such as 18. Although, Schweich Jr. et al. do not explicitly recite to substantially close off a lower or apical portion only of only a left ventricle of the patient's heart, it is well within the scope of the invention and would be obvious to one with ordinary skill in the art to assure that the device of Schweich, Jr. et al. is drawn tightly enough to bring the walls into contact for the purpose of further treating congestive heart disorder by closing off the lower portion of the left ventricle.

Regarding claim 11, Schweich, Jr. et al. as modified disclose that as applied to claim 10, as well as, deploying of the tensile member that includes anchoring one end of the tensile member to a septum of the patient's heart and an opposite end of the tensile member to a myocardial sidewall of the left ventricle, as recited in columns 7-8 and seen in figures such as 18.

Regarding claim 17, Schweich, Jr. et al. as modified disclose that as applied to claim 10, as well as, deployment of the tensile member that includes placing sufficient tension on the tensile member in the patient's heart so as to bring in opposing inner surface of the left ventricle to thereby effectively constrict the lower or apical portion of the left ventricle of the patient's heart, as recited in columns 7-8 and seen in figures such as 18. Although not explicitly recited, bringing in opposing inner surfaces of the left ventricle into substantial contact with one another to thereby effectively constrict and substantially close off the lower or apical portion of the left ventricle of the patient's heart it is well within the scope of the invention and would be obvious to one with ordinary skill in the art to assure that the device of Schweich, Jr. et al. is drawn tightly enough to bring the walls into contact for the purpose of further treating congestive heart disorder by closing off the lower portion of the left ventricle.

4. Claims 8, 16, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schweich, Jr. et al. in US Patent No. 5,961,440 in view of Huebsch et al. in US Patent No. 5,853,422.

Regarding claim 8, Schweich, Jr. et al. as modified disclose that as applied to claim 7. However, Schweich, Jr. et al. do not explicitly recite introduction of the tensile member that includes passing a leading end portion of the catheter into a right ventricle of the patient's heart, the operating of the compressive device that includes ejecting the tensile

member from the leading portion end portion of the catheter through a septum and a left ventricle and a myocardial wall of the patient's heart, the operating of the compressive device further including exerting a tension force on the tensile member to draw the septum and myocardial wall together. On the other hand, Huebsch et al. teach introduction of a closure member that includes passing a leading end portion of the catheter 40) into a right ventricle of the patient's heart, the operating of the closure member that includes ejecting the member from the leading portion end portion of the catheter through a septum and a left ventricle and a myocardial wall of the patient's heart. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Schweich et al. to use the deployment technique of Huebsch et al. for the purpose of a less invasive insertion of a device to close the lower portion of the left ventricle. This combination would necessarily require the operating of the compressive device further including exerting a tension force on the tensile member to draw the septum and myocardial wall together.

Regarding claim 16, Schweich, Jr. et al. as modified disclose that as applied to claim 10. However, Schweich, Jr. et al. do not recite deploying of the tensile member that includes inserting a leading end portion of a catheter into a vascular system of the patient and into a ventricle of the patient's heart; ejecting the tensile member from the leading end portion of the catheter into the heart tissue so that the tensile member is anchored to the patient's heart tissue; and exerting tension on the tensile member to pull a septum and a myocardial sidewall of the left ventricle of the patient's heart toward

one another so as to constrict and substantially close off only a lower or apical portion of only the patient's left ventricle. On the other hand, Huebsch et al. teach deploying a closure member that includes inserting a leading end portion of a catheter (40) into a vascular system of the patient and into a ventricle of the patient's heart and ejecting the member from the leading end portion of the catheter into the heart tissue so that the tensile member is anchored to the patient's heart tissue. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Schweich et al. to use the deployment technique of Huebsch et al. for the purpose of a less invasive insertion of a device to close the lower portion of the left ventricle. This combination would necessarily require exerting tension on the tensile member to pull a septum and a myocardial sidewall of the left ventricle of the patient's heart toward one another so as to constrict and substantially close off only a lower or apical portion of only the patient's left ventricle.

Regarding claim 18, Schweich, Jr. et al. disclose a method for reducing ventricular volume via deploying a cardiac insert or implant (such as 16 with 20, etc.) from the leading portion of a catheter (such as 60); and disposing the cardiac insert or implant in the patient's heart to reduce the volume of only a left ventricle of the patient's heart, as recited in columns 7-9 and seen in figures such as 18. However, Schweich, Jr. et al. do not explicitly recite inserting a leading end portion of a catheter through part of a patient's vascular system and into a ventricle of the patient's heart. On the other hand, Huebsch et al. teach inserting a leading end portion of a catheter (40) through part of a

patient's vascular system and into a ventricle of the patient's heart. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Schweich et al. to use the deployment technique of Huebsch et al. for the purpose of a less invasive insertion of a device to close the lower portion of the left ventricle.

Regarding claim 19, Schweich, Jr. et al. as modified by Huebsch et al. disclose that as applied to claim 18. Further, Schweich, Jr. et al. also disclose a cardiac insert or implant that is a tensile member, further attaching the tensile member to the patient's heart and exerting tension on the tensile member to draw a septum of the patient's heart and a myocardial sidewall of the patient's left ventricle towards one another at a lower end of the left ventricle, as recited in columns 7-9 and seen in figures such as 18.

5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schweich, Jr. et al. in US Patent No. 5,961,440 in view of Vinlund et al. in US Patent No. 6,537,198.

Regarding claim 14, Schweich, Jr. et al. as modified disclose that as applied to claim 10. However, Schweich, Jr. et al. do not recite a tensile member that is a tack. On the other hand, Vinlund teaches a tack (such as 65), as seen in figure 12. Therefore, it would be obvious to one with ordinary skill in the art to further modify the invention of Schweich et al. to include a tack where the deploying of the tensile member that

includes ejecting the tack from a tubular member, as taught by Vinlund et al. for the purpose of properly securing the device to the heart.

6. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schweich, Jr. et al. in US Patent No. 5,961,440 in view of Huebsch et al. in US Patent No. 5,853,422 and further in view of Vinlund et al. in US Patent No. 6,537,198.

Regarding claim 20, Schweich, Jr. et al. as modified by Huebsch et al. disclose that as applied to claim 19. However, a tensile member that is provided with at least one barb at a leading end, attaching the tensile member to the patient's heart via embedding the bard into the patient's heart is not recited. On the other hand, Vinlund teaches a tack (such as 65), as seen in figure 12. Therefore, it would be obvious to one with ordinary skill in the art to further modify the invention of Schweich et al. to include a tack where the deploying of the tensile member that includes ejecting the tack from a tubular member, as taught by Vinlund et al. for the purpose of properly securing the device to the heart.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-3, 7, 8, 10, 11, 13, 14, and 16-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 09/900,126. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely a reworded representation for the same subject matter perhaps slightly broader in some aspects while slightly more narrow in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-3, 7, 8, 10, 11, 13, 14, and 16-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,572,529. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely a reworded representation for the same subject matter perhaps slightly broader in some aspects while slightly more narrow in others.

10. Claims 1, 7, and 8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 19 of U.S. Patent No. 6,258,021. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely a reworded representation

for the same subject matter perhaps slightly broader in some aspects while slightly more narrow in others.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US 2003/0102000; US Patent No. 6,629,921; US Patent No. 6,616,684; US Patent No. 6,260,552; US Patent No. 6,171,329; and US Patent No. 5,879,366.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KO

Henry Bennett
Supervisory Patent Examiner
Group 3700